UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,624	01/31/2002	David H. Walker	D6152CIP2/D1	4747

7590 07/30/2003

Benjamin Aaron Adler, Ph.D., J.D.
Adler & Associates
8011 Candle Lane
Houston, TX 77071

EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	PAPER NUMBER
1645	7

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/062,624	Applicant(s) WALKER ET AL.	
	Examiner Padmavathi v Baskar	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12 and 13* is/are pending in the application.

4a) Of the above claim(s) *13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *12-13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's response to restriction filed on 5/2/03 is acknowledged. No claims have been canceled. No claims have been added or amended. Claims 12-13 are pending in the application.

Priority

2. This application is a DIV of 09/660,587, 09/12/2000 PAT 6,392,023, which is a CIP of 09/261,358, 03/03/1999 PAT 6,403,780, which is a CIP of 09/201,458 11/30/1998 PAT 6,458,942 is acknowledged.

Applicants have first disclosed the SEQID.NO: 40 in the priority application 09/660,587, 09/12/2000. Therefore, claim 12, drawn to a recombinant protein, SEQ.ID.NO: 40 gets priority as of 09/12/2000.

Applicant is advised to update the status of the U.S.Applications in the Specification.

Drawings

3. The drawings are accepted by the draftsperson under 37 C.F.R. 1.84 or 1.152

Information Disclosure Statement

4. No Information Disclosure Statement has been filed with this application.

Election

5. Applicant's election of Group IV claim 12-13 with traverse with respect to SEQ.ID.NO: 40 in Paper # 6 is acknowledged.

The traversal is on the ground(s) that (1) the protein species in group I –VII are integrally related and SEQ.ID.NOS: 2, 4, 6, 40,42, 44 and 46 represent the products of p28 genes within a single multigene locus in *E.chaffeensis,* (2) besides being related by significant sequence

identity, the genes in the p28 locus function together to escape the immune response, (3) the expression of genes is varied and in turn vary presentation of p28 antigens and (4) search of the prior art would not unduly burden the examiner.

As applicant pointed out all these cDNA are from different species and not related to each other and are considered as patentably distinct inventions. This is not found persuasive because (1) applicant has not shown how these proteins are integrally related and to what? Applicant rightly pointed out that SEQ.ID.NOs: 12, 4, 6, 40, 42, 44 and 46 represent various products of p28 genes. Whether these genes are within a single multigene locus is irrelevant because each gene encodes a different product, i. e., SEQ.ID.NO 2 or 4 etc. (2) Further, the examiner has established that the Inventions SEQ ID NO: 2, 4, 6,40,42,44 and 46 Inventions are unrelated and have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions; represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects. Thus, each sequence is unique and patentably distinct since each sequence has a different structure with specific amino acid or nucleic acid and is identified by a specific SEQ.ID.NO. Immune response as a whole is not a single function because immune response is mediated by various cell types namely T cells, B-cells, Monocytes, eosinophils etc and respond to a protein differently in mediating antibody response or cell mediated response. (3) Again applicant correctly identifies that the expression of genes is varied and in turn presentation of P28 antigen varies structurally and functionally resulting in various sequences (SEQ ID NO: 2, 4, 6,40, 42, 44 and 46). (4) Further, the restriction of sequences has acquired a separate status in the art as a separate subject for inventive effect and requires independent searches. The search for each of the above inventions is not co-extensive particularly with

regard to the literature search. A reference, which would anticipate the invention of one SEQ.ID.NO, would not necessarily anticipate or make obvious any of the other SEQ.ID.NO. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist. Restriction is deemed proper because these products appear to constitute patentably distinct inventions and is therefore made FINAL

6. Claim 13 is withdrawn because the elected invention is not drawn to the nucleic acid sequences, said election made in paper # 6.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Rikihisa et al 1999, Accession Number: AAYO69965 (WO9913720).

The claim is directed to a recombinant protein comprises of an amino acid sequence SEQ.ID.NO: 40.

Rikihisa et al disclose an isolated protein p30-5 (see claim 19 of WO9913720) comprising an amino acid sequence identical to the claimed recombinant protein (see Figure 25B of WO9913720) SEQ.ID.NO: 40. A sequence alignment indicates (see attached sequence

alignment of AAYO69965 as represented by Db with SEQ.ID.NO: 40 as represented by Qy) that p30-5 is 100% identical of the present invention.

It is noted that claim 12 contains product-by-process claim language. Applicants are advised that the process limitations cannot be relied upon for patentability and that the patentability of the subject matter is being assessed based upon the product and it's attendant properties. *In re Marosi*, 710 F.2d 799, 218 U.S.P.Q. 289 (Fed. Cir. 1983). *Scripps Clinic & Res. Found.* v. Genentech, *Inc.*, 927 F.2d 1565, 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991). Here, the outer-membrane protein p30-5 is identical in structure to the claimed recombinant protein.

The recitation of a process limitation (recombinant) in claim 12 is not seen as further limiting the claimed product, as it is presumed the equivalent products can be obtained by multiple methods. Where a product-by-process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden is upon the applicants to provide evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Thorpe*, 227 U.S.P.Q. 964, 966 (Fed. Cir. 1985). *In re Marosi*, 218 U.S.P.Q. 289, 293-293 (C.A.F.C. 1983). *In re Best*, 195 U.S.P.Q. 430, 433 (C.C.P.A. 1977). *In re Brown*, 173 U.S.P.Q. 685, 688 (C.C.P.A. 1972).

9. Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Accession Number: AF082744.

The claim is discussed supra.

Accession number AF082744 disclose a protein comprising an amino acid sequence identical to the claimed recombinant protein SEQ.ID.NO: 40.

Please note the translation product of nucleic acid sequence from nucleotides 170-1048 of AF082744 (see the alignment of SEQ.ID.NO: 40 as represented by Qy with the AF082744 as represented by Db) is identical to SEQ.ID.NO 40.

A sequence alignment indicates that the protein disclosed is 100% identical of the present invention.

10. Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Accession Number: AF078553.

The claim is discussed supra.

Accession number AF078553 disclose a protein comprising an amino acid sequence identical to the claimed recombinant protein SEQ.ID.NO: 40.

Please note the translation product of nucleic acid sequence from nucleotides 14133 - 15011 of AF078553 (see the alignment of SEQ.ID.NO: 40 as represented by Qy with the AF082744 as represented by Db) is identical to SEQ.ID.NO 40.

A sequence alignment indicates that the protein disclosed is 100% identical of the present invention.

It is noted that claim 12 contains product-by-process claim language. Applicants are advised that the process limitations cannot be relied upon for patentability and that the patentability of the subject matter is being assessed based upon the product and it's attendant properties. *In re Marosi*, 710 F.2d 799, 218 U.S.P.Q. 289 (Fed. Cir. 1983). *Scripps Clinic & Res. Found.* v. Genentech, *Inc.*, 927 F.2d 1565, 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991). Here, the outer-membrane protein p30-5 is identical in structure to the claimed recombinant protein.

The recitation of a process limitation (recombinant) in claim 12 is not seen as further limiting the claimed product, as it is presumed the equivalent products can be obtained by multiple methods. Where a product-by-process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden is upon the applicants to provide evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Thorpe*, 227 U.S.P.Q. 964, 966 (Fed. Cir. 1985). *In re Marosi*, 218

U.S.P.Q. 289, 293-293 (C.A.F.C. 1983). *In re Best*, 195 U.S.P.Q. 430, 433 (C.C.P.A. 1977). *In re Brown*, 173 U.S.P.Q. 685, 688 (C.C.P.A. 1972).

Status of claims

11. Claim 12 is rejected.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D

7/20/03

NITA MINNIFIELD
PRIMARY EXAMINER
7/24/03